Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of supervised rehabilitation on gait symmetry and regularity after acute ankle sprain

Protocol summary

Study aim
Determining the effect of supervised rehabilitation on gait symmetry and regularity after acute ankle sprain

Design
Quasi-experimental, pretest-posttest, single-group, non-randomized clinical trial, with a healthy reference group without intervention for comparison with normative values. On 16 patients, unblinded.

Settings and conduct
This study will be conducted on 16 patients with acute ankle sprain. This is a quasi-experimental clinical trial with a pre-post design; therefore, randomization or blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged between 18 and 50 years, Patients with Grade 1 or 2 ankle sprain, Patients with an acute ankle sprain, meaning the injury occurred between 7 days and 1 month ago, Presence of symptoms such as swelling or pain on the lateral side of the ankle, limited ankle range of motion, and tenderness over the lateral ligaments, Minimum literacy level, with the ability to read and write at least at a middle school level

Intervention groups
The intervention group will receive 10 supervised ankle rehabilitation sessions. Each intervention session, which includes electrotherapy and therapeutic exercises, will last between 1.5 to 2 hours. Overall, the therapeutic exercises will include strengthening, neuromuscular, range of motion, and balance exercises. The duration of electrotherapy in each session will be between 15 to 30 minutes, using TENS (Transcutaneous Electrical Nerve Stimulation). Strengthening exercises for the muscles around the ankle will be performed using resistance bands of varying levels. Balance and proprioception exercises will be conducted using a balance board and other related equipment.

Main outcome variables
step regularity; stride regularity; gait symmetry

General information

Reason for update
The inclusion age range was updated from 18–50 years to 18–55 years, as patients older than 50 years who met all other inclusion criteria (physician-diagnosed Grade I or II acute lateral ankle sprain) presented during the data collection period. In addition, the achieved sample size is being recorded as 15 participants per group (patient and healthy reference groups), reflecting attrition during study conduct.

Acronym

IRCT registration information
IRCT registration number: **IRCT20250503065584N1**
Registration date: **2025-08-07, 1404/05/16**
Registration timing: **prospective**

Last update: **2026-08-22, 1405/05/31**
Update count: **2**

Registration date
2025-08-07, 1404/05/16

Registrant information

Name
Melika Shameli

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-22, 1404/05/31

Expected recruitment end date
2025-11-21, 1404/08/30

Actual recruitment start date
2025-08-11, 1404/05/20
Actual recruitment end date
2026-01-20, 1404/10/30
Trial completion date
2026-01-20, 1404/10/30

Scientific title
Investigating the effect of supervised rehabilitation on gait symmetry and regularity after acute ankle sprain

Public title
The effect of rehabilitation on gait symmetry and regularity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged between 18 and 55 years Patients with Grade 1 or 2 ankle sprain Patients with an acute ankle sprain, meaning the injury occurred between 7 days and 1 month ago Presence of symptoms such as swelling or pain on the lateral side of the ankle, limited ankle range of motion, and tenderness over the lateral ligaments Minimum literacy level, with the ability to read and write at least at a middle school level
Exclusion criteria:
Patients with syndesmotic injury in addition to the ankle sprain. Patients with a history of surgery or fracture in the lower limbs within the past year. Patients who had sustained an acute injury to the musculoskeletal structures of other lower limb joints within the past three months that affected joint integrity and function—such as a sprain or fracture—and had missed at least one day of their usual physical activity. Patients with neurological disorders such as stroke, multiple sclerosis (MS), or neuropathy. Individuals who had experienced an ankle sprain within the past 12 months. In the treatment of ankle sprains, initial protection is typically provided for one to two weeks, followed by the use of bandages or tape, which does not interfere with our study. However, patients using foot or ankle orthoses were excluded from the study.
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
Actual sample size reached: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Deputy of Research and Technology, Central Headquarters Building, Iran University of Medical Sciences, Hemmat Expressway, next to Milad Tower, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2025-05-14, 1404/02/24
Ethics committee reference number
IR.IUMS.REC.1404.159

Health conditions studied

1

Description of health condition studied
Acute ankle sprain
ICD-10 code
S93.4
ICD-10 code description
Sprain of ankle

Primary outcomes

1

Description
Step regularity based on trunk acceleration
Timepoint
Before the intervention and immediately after the tenth session of supervised ankle rehabilitation.
Method of measurement
The Phyphox software installed on the mobile phone

2

Description
Stride regularity based on trunk acceleration
Timepoint
Before the intervention and immediately after the tenth session of supervised ankle rehabilitation.

Method of measurement
The Phyphox software installed on the mobile phone

3

Description
Gait symmetry based on trunk acceleration
Timepoint
Before the intervention and immediately after the tenth session of supervised ankle rehabilitation.
Method of measurement
The Phyphox software installed on the mobile phone

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group:In this study, the intervention consists of supervised ankle rehabilitation. Supervised ankle rehabilitation refers to the use of electrotherapy and exercise therapy based on current guidelines. The rehabilitation program will be conducted over 10 sessions (approximately 3 sessions per week). The duration of electrotherapy in each session will range from 15 to 30 minutes (using TENS current). Each intervention session, which includes both electrotherapy and exercise therapy, will last between 1.5 to 2 hours.In general, the exercise therapy includes strengthening, neuromuscular, range of motion, and balance exercises. Strengthening exercises for the muscles surrounding the ankle will be performed using resistance bands of varying levels. Balance and proprioception training will be carried out using a balance board and other equipment.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar hospital
Full name of responsible person
Melika Shameli
Street address
Akhter Advanced Subspecialty Orthopedic Center, Azar Dead End, Sharifi Manesh Street, Pol-e Roomi Street, Shariati Street, Tehran, Iran
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2

Recruitment center
Name of recruitment center
School of Rehabilitation, Iran University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid Safa
Street address
5th Floor, Central Headquarters, Iran University of Medical Sciences, Hemmat Expressway, Next to Milad Tower, Tehran, Iran
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safa.m@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Melika Shameli

Position

Master's student in Physiotherapy

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Professor

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Person responsible for updating data

Contact

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Melika Shameli

Position

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Latest degree

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Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We do not have ethical approval for this purpose.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available